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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/236,468	01/25/99	SOPPET	D PF201D1

EXAMINER

HM22/0315

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ART UNIT	PAPER NUMBER
SPECTOR, L	
1646	4

DATE MAILED: 03/15/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-20 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-404-496/40517

Part III: Detailed Office Action

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to nucleic acids, vectors, host cells, and expression, classified in class 435, subclass 69.1.

II. Claims 8 and 9, drawn to protein, classified in class 350, subclass 350.

III. Claim 10, drawn to antibody, classified in class 530, subclass 387.9.

IV. Claims 11 and 13, drawn to agonists, classification dependent upon species.

V. Claims 12 and 14, drawn to antagonists, classification dependent upon species.

VI. Claim 15, drawn to gene therapy using DNA encoding an agonist, classified in class 514, subclass 44.

VII. Claim 16, drawn to gene therapy using DNA encoding an antagonist, classified in class 514, subclass 44.

VIII. Claims 17-18 and 20, drawn to assays for binding agents, classified in class 435, subclass 7.2.

IX. Claim 19, drawn to a diagnostic method using nucleic acids, classified in class 435, subclass 6.

The inventions are distinct, each from the other because:

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in claim 6. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid

hybridization assay.

The nucleic acids of Invention I are separate and distinct from the antibodies of invention III, the agonists of invention IV and the antagonists of invention V, wherein the groups have different chemical structures, functions, uses, and means of manufacture, and wherein neither is required for the other.

The nucleic acids of Invention I are separate and distinct from the method of inventions VI, VII, and VIII, wherein the nucleic acids are not made by nor required for the methods.

Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used for recombinant production of protein, as evidenced by claim 6.

The proteins of Invention II are related to the antibodies of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (as the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The proteins of invention II, the agonists of invention IV and the antagonists of invention V are mutually separate and distinct, wherein the three groups are drawn to mutually exclusive groups of matter, which differ in structure and function, and which require divergent searches.

The proteins of Invention II are separate and distinct from the methods of inventions VI, VII and IX, wherein the proteins are neither made by nor used in the methods.

Inventions II and VIII are related as product and process of use. The inventions can be shown

to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins can be used for the production of the antibodies of invention III.

The antibodies of invention III are separate and distinct from the agonist and antagonist of inventions IV and V, respectively. Although some antibodies may have agonist or antagonist activity, such would comprise a small minority of the antibodies, and further, neither of inventions IV or V requires an antibody. Accordingly, restriction is proper.

The antibodies of invention III are separate and distinct from the methods of inventions VII-IX, wherein the antibodies are neither made by nor used in the methods.

Invention IV is separate and distinct from invention VI, and invention V is separate and distinct from Invention VII because the agonist or antagonist is a substantively different chemical entity from the DNA which encodes it, as the two have different chemical structures and functions, and require different searches. Accordingly, the method of using the DNA is similarly separate and distinct from the agonist or antagonist itself.

Inventions IV and V are separate and distinct from the methods of each of inventions VIII and IX, wherein the products of Inventions IV and V can neither be made by nor used in the methods.

The methods of inventions VI, VII, VIII and IX are each separate and distinct from the others, wherein the various methods required different method steps and/or reagents, and have different purposes and outcomes, and thus require separate or divergent searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

Lorraine Spector, Ph.D.
Primary Examiner

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